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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,035	06/22/2001	Atsunori Fukuda	SPO-115C1	9222

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,035	FUKUDA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *10-13,26 and 27* is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *1-3,5-9,14-25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-9, 14-25 and 28 in Paper No. 8 is acknowledged. Claims 10-13 and 26-27 are withdrawn from consideration.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed January 7, 2002, Paper No. 6, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 5, 8, 9, 19-23, 25 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a DNA encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added, and a DNA hybridizing under stringent conditions to SEQ ID NO:1, as well as to vectors, cells and plants comprising said DNA. The claims are also drawn to a nucleic acid that hybridizes with the DNA of SEQ ID NO:1 and which has a chain length of at least 15 nucleotides.

The specification describes a cDNA of SEQ ID NO:1 obtained from rice encoding the amino acid sequence set forth in SEQ ID NO:2 (sequence listing). The specification also describes the amino acid sequence set forth in SEQ ID NO:2 as having homology to yeast NHX1 and mammalian NHE Na^+/H^+ antiporter proteins, and characterizes the protein of SEQ ID NO:2 as having an Na^+/H^+ antiporter function as evidenced by complementation of nhx1 mutant yeast (pages 19-23). The specification does not describe or characterize any nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added, or any nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO:1, or any nucleic acid that hybridizes with the DNA of SEQ ID NO:1 and which has a chain length of at least 15 nucleotides.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of

written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims are 18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a transformant plant that is the offspring or clone of a transformant plant comprising a transformant cell comprising DNA of SEQ ID NO:1 or encoding SEQ ID NO:2 or encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added or hybridizing under stringent conditions to SEQ ID NO:1.

The claimed invention lacks written description under current written description guidelines. The claim is drawn to progeny plants having undisclosed identifying characteristics whereby only one parent is known. Applicant should note that no identifying characteristics are set forth for the progeny. If the claimed progeny plant itself cannot be identified by characteristics clearly disclosed in the specification, then it would be impossible to determine whether or not a plant of unknown parentage is covered by the claim. Thus progeny plants which are not disclosed by any identifying characteristics are not considered to be possessed by

Applicant. Absent further guidance, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genotypic or phenotypic characteristics of the progeny plants obtained. Breeding techniques can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring are highly unpredictable, especially in view of the fact that no identifying characteristics for the progeny plants are disclosed in the specification or set forth in the claims. Furthermore, while the claim recites that the claimed transformant plant is the offspring or clone of a transformant plant comprising a transformant cell comprising a particular DNA sequence, the claim does not require that the claimed transformed plant also comprise the particular DNA sequence of the parental transformant plant, which may or may not transmit the particular DNA sequence to its clone or offspring. Accordingly, there is a lack of written description for the claimed progeny plants, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed progeny (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 2, 3, 5, 8, 9, 19-23, 25 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA of SEQ ID NO:1 or an isolated DNA encoding the amino acid sequence of SEQ ID NO:2, and vectors, cells and plants comprising said DNA, does not reasonably provide enablement for a DNA encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added, or a DNA hybridizing under low or moderately stringent conditions to SEQ ID NO:1, or a nucleic acid that hybridizes under unspecified conditions with the DNA of

SEQ ID NO:1 and which has a chain length of at least 15 nucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a DNA encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added, and a DNA hybridizing under low or moderately stringent conditions to SEQ ID NO:1, as well as to vectors, cells and plants comprising said DNA. The claims are also drawn to a nucleic acid that hybridizes under unspecified conditions with the DNA of SEQ ID NO:1 and which has a chain length of at least 15 nucleotides.

The specification discloses the cloning of a cDNA of SEQ ID NO:1 obtained from rice encoding the amino acid sequence set forth in SEQ ID NO:2 (pages 19-22). The specification also discloses that the amino acid sequence set forth in SEQ ID NO:2 has homology to yeast NHX1 and mammalian NHE Na^+/H^+ antiporter proteins, and has an Na^+/H^+ antiporter function as evidenced by complementation of nhx1 mutant yeast (pages 19-23). Additionally, the specification discloses the production of transgenic rice plants comprising SEQ ID NO:1 (page 22). The specification does not disclose how to make specific substitutions, deletions, insertions or additions to SEQ ID NO:2 such that the encoded protein would retain its Na^+/H^+ antiporter function. The specification does not disclose the isolation of sequences that hybridize with a nucleic acid of SEQ ID NO:1 under low or moderately stringent conditions and that encode a protein that has Na^+/H^+ antiporter function.

Guidance for making and using the claimed invention is necessary for enablement because it is unpredictable whether a DNA molecule encoding an amino acid sequence of SEQ

ID NO:2 that has had an undetermined number of substitutions, deletions, insertions and/or or additions will encode a functional polypeptide. It is also unpredictable whether a sequence that hybridizes under undefined stringency conditions to SEQ ID NO:1 will encode a functional polypeptide. A change in as few as one nucleotide in a base sequence, such as would occur by deletion, addition, substitution, or as a consequence of hybridization can alter the amino acid sequence of the encoded polypeptide, and a change in as few as one amino acid in a polypeptide can alter or eliminate its function. For example, Rhoads et al. (J. Biol. Chem., November 1998, Vol. 273, No. 46, pages 30750-30756) teach that mutation of Cys-128 to Ala in an *Arabidopsis* alternative oxidase caused a pronounced overall increase in enzyme activity relative to the wild-type in the presence or absence of pyruvate (page 30753 Figure 3). Mutation of Cys-78 to Ala in the same *Arabidopsis* alternative oxidase resulted in a minimally active enzyme that showed no response to added pyruvate (page 30753 Figure 3).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed nucleic acid sequences would encode a functional and therefore useful polypeptide.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, 7, 8, 19, 23 and 25, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 5, 8, 19, 23 and 25, and claims dependent thereon, are indefinite in the recitation of "derived from monocotyledonae", because it is unclear how a DNA can be derived from an entire class of plants. It is suggested that the claim be amended to indicated that the DNA is obtained from a monocotyledonous plant.

Claims 2, 5, 8, 19, 23 and 25, and claims dependent thereon, are indefinite in the recitation of "stringent conditions". It is unclear what conditions would yield the claimed nucleic acid molecules because those skilled in the art define "stringent conditions" differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 7 is indefinite for depending on itself.

Claim Rejections - 35 USC § 101

Claims 1-3 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to DNA.

Claims 1-3 and 28, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated DNA" or "Purified DNA". See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 5-9, 14-25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiei et al. (The Plant Journal, 1994, Vol. 6, No. 2, pages 271-282).

The claims are drawn to a DNA encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added, and a DNA hybridizing under stringent conditions to SEQ ID NO:1, or to any DNA which hybridizes to SEQ ID NO:1 under conditions of unspecified stringency, as well as to vectors, rice cells and rice plants comprising said DNA. The claims are also drawn to a transformant rice plant or monocotyledonous plant cell comprising DNA comprising the coding region of SEQ ID NO:1 or a DNA encoding a protein consisting of the amino acid sequence of SEQ ID NO:2.

Hiei et al. teach a vector comprising DNA encoding GUS, as well as rice cells and rice plants comprising said DNA (page 280 column 1 *Bacterial strains and plasmids* and page 273 Figure 2). While Hiei et al. do not explicitly teach any relationship between the DNA encoding GUS and SEQ ID NOS: 1 and 2, no such relationship need be taught or established. The claims do not limit the number or nature of amino acid substitutions, deletions, insertions or additions made to the amino acid sequence of SEQ ID NO:2, such that the claims read on any DNA encoding any amino acid sequence. Furthermore, Hiei et al. teach a transformant rice plant or monocotyledonous plant cell comprising DNA comprising the coding region of SEQ ID NO:1 or a DNA encoding a protein consisting of the amino acid sequence of SEQ ID NO:2, because the transformant plants and plant cells taught by Hiei et al. are rice plants and plant cells. While Hiei et al. do not teach transformation with DNA comprising the coding region of SEQ ID NO:1 or a DNA encoding a protein consisting of the amino acid sequence of SEQ ID NO:2, no such requirement is imposed by the claims. The claims do not recite that the plant or plant cell is transformed with SEQ ID NO:1 or that it comprises an isolated SEQ ID NO:1. The claims require only that the plant or plant cells be transformant, and that the plant or plant cell comprise DNA comprising the coding region of SEQ ID NO:1 or a DNA encoding a protein consisting of the amino acid sequence of SEQ ID NO:2. Since all rice plants and plant cells inherently comprise a DNA comprising the coding region of SEQ ID NO:1 or a DNA encoding a protein consisting of the amino acid sequence of SEQ ID NO:2, the claims read on any transformant rice plant or plant cell, regardless of the identity of the DNA sequence used for transformation.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (GenBank Accession No. C91832, 20 April 1998, Applicant's IDS).

The claim is drawn to a nucleic acid that hybridizes with the DNA of SEQ ID NO:1 and which has a chain length of at least 15 nucleotides.

Sasaki et al. teach a nucleic acid that hybridizes with the DNA of SEQ ID NO:1 and which has a chain length of at least 15 nucleotides, by virtue of 95% local similarity thereto (see enclosed sequence search report).

Claims 18 and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiei et al. (The Plant Journal, 1994, Vol. 6, No. 2, pages 271-282).

The claims are drawn to a transformant plant that is the offspring or clone of a transformant plant comprising a transformant cell comprising DNA of SEQ ID NO:1 or encoding SEQ ID NO:2 or encoding the amino acid sequence of SEQ ID NO:2 wherein one or more amino acids are substituted, deleted, inserted and/or added or hybridizing under stringent conditions to SEQ ID NO:1.

Hiei et al. teach a transformant plant (page 273 Figure 2). There are insufficient identifying characteristics set forth in the claims to distinguish the claimed progeny plants from the transgenic plants of the prior art. The claims do not specifically recite a progeny plant whereby all of the identifying characteristics of the parent plant are retained. The breeding techniques used to produce the claimed progeny plants can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring

are highly unpredictable. None of the identifying features which distinguish Applicant's plants from those of the prior art are set forth (see written description rejection *supra*). Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of any prior art that teaches transgenic plants. See in re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process of making the product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See In re Best, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977).

Remarks

Claim 4 is allowed.

Claim 4 is deemed free of the prior art, given the failure of the prior art to teach or suggest a vector comprising isolated nucleic molecules comprising SEQ ID NO:1 or encoding SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 16, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638